REMARKS

Claims 1 and 2 are presently rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner indicates that in claim 1, the phrase "compound comprising gabapentin" is vague and indefinite because the term "comprising" would mean that there are other additional components besides gabapentin. In response to this rejection, Applicants amend claims 1 and 2 by deleting "a chemical compound, comprising" and claim only "gabapentin tannate". Applicants believe that claims 1 and 2 now meet all of the requirements of 35 U.S.C. § 112, second paragraph, and accordingly, this rejection should be withdrawn.

Claims 1-2 and 5-21 are presently rejected under 35 U.S.C. § 103(a) as being obvious over Satzinger et al. (U.S. 4,024,175) in view of Gould (International J. of Pharmaceutics, vol. 33 (1986), pp. 201-217). Applicants' arguments filed 12/02/04 have been fully considered but were found not persuasive. The rejection of claims 1-2 and 5-21 under U.S.C. § 103(a) has been maintained for the reasons of record on 9/15/04. Briefly, to summarize the U.S.C. § 103(a) rejection of 9/15/04, the Examiner indicates that the Satzinger et al. reference discloses the preparation of gabapentin and pharmacologically compatible salts; but does not disclose the preparation of gabapentin tannate salts.

Turning to Gould, the Examiner notes that Gould discloses a list of anions, including tannate, that have been FDA approved for commercially marketed drugs (Table 1 on page 202 is a listing of 54 approved anions of which tannate is one). The Examiner does not mention that Gould further teaches that the monoprotic hydrochlorides have been by far the most frequent choice of the available anionic salt-forming species. Hydrochloride salts have a 43% selection rate compared to the tannate salts at a selection rate of 0.88%. Only if there are problems arising out of the use of hydrochloride salts does Gould suggest seeking another salt selection. No where in the Gould reference is there a suggestion that the tannate salts could be used with gabapentin. Furthermore, the Gould reference includes an appendix which is a compilation of the characteristics of various salt forming acids and examples of their use with selected active ingredients. It should be noted that tannate salts are conspicuously absent.

In view of the foregoing, on what basis other than improper hindsight does the Examiner conclude that a person skilled in the art, at the time the invention was made, would be motivated to prepare tannate salts of the very well known drug gabapentin?

Based on the above discussion of the two references, which were combined to reject claims 1-2 and 5-21 under 35 U.S.C. § 103(a), Applicants assert that the Examiner has failed to establish a prima facie case of obviousness. The Federal Circuit has expressed its view in *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992) that if at the initial stage of examination the Examiner does not establish a prima facie

case of unpatentability then, without more, the Applicant is entitled to grant of the patent. While the "Elements" of the prima facie case of obviousness have not been expressed in any formal manner, five Elements have emerged over the years, as defined by a history of Federal Circuit decisions[1], as necessary to establish a prima facie case of obviousness. The Elements that an Examiner must provide are:

1. one or more references
2. that were available to the inventor and
3. that teach
4. a suggestion to combine or modify the references,
5. the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art.

Accordingly, an Applicant who is able to prove that the Examiner has failed to establish any one of these Elements will prevent the prima facie case of obviousness from being established. *(See: Donner, Irah H., Patent Prosecution: Practice & Procedure Before the U.S. Patent Office, Second Edition, March 2002, at page 505)*

Using these Elements as a guideline, it appears that Elements 1 and 2 have been met, i.e., the Examiner has cited one or more references that were available to the inventor. Element 3 of the prima facie case, however, is not met. As discussed above, the cited references actually teach away from preparing a gabapentin tannate salt.

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[1] *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992); In re Gurley, 27 F.3d 551, 553, 31 USPQ 2d 1130 (Fed. Cir. 1994); *C. R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998); *Smith's Indus. Med. Sys., Inc. v. Vital Signs Inc.*, 51 USPQ 2d 1415, 1420-21 (Fed. Cir. 1999).

Satzinger et al. teaches the preferred use of the hydrochloride salt while Gould points out the relative infrequent use of tannate as a salt for active pharmaceutical ingredients. As a general rule, references that teach away cannot serve to create a prima facie case of obviousness. In re Gurley, 27 F.3d 551, 553, 31 USPQ 2d 1130 (Fed. Cir. 1994).

With regard to Elements 4 and 5, the Federal Circuit case law makes it clear that the best defense against a hindsight-based obviousness analysis is a showing that the teaching or motivation to combine prior art references is lacking. *C. R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). In *Smith's Indus. Med. Sys., Inc. v. Vital Signs Inc.*, 51 USPQ 2d 1415, 1420-21 (Fed. Cir. 1999), the Court indicated that there is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention. On the contrary, the relevant inquiry is whether there is (1) a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and (2) a suggestion of a reasonable likelihood of success. As discussed above, the cited references, rather than suggesting a reasonable likelihood of success, actually suggest that it would have been unlikely that a gabapentin tannate salt would have been a successful combination.

Furthermore, Applicants would like to direct the Examiner to page 1 of the present application where the formation of a tannate salt of gabapentin is discussed as being unexpected because of the close proximity of a carboxylic acid group to the amine group.

The negative charge on the carboxylic acid group was expected to shield and possibly neutralize a positive charge on the proximal nitrogen. Since tannate salts are thought to normally form through an ionic interaction with a positively charged amine functional group, the close proximity of the carboxylic acid group was expected to prevent the formation of a tannate salt.

Applicants further assert the arguments presented in Applicants' communication of December 2, 2004, based on the Satzinger et al. patent having issued over 27 years ago and the Gould reference being published about 18 years ago. Applicants incorporate herein the argument that the failure of others to prepare gabapentin tannate should be considered in conjunction with both the passage of 18 years and significant marketplace pressures to produce new pharmaceutical products.

Based on the foregoing, the rejection of claims 1 and 2 and 5-21 under 35 U.S.C. § 103 should fail and the claims of the present application should be allowed.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being sent by facsimile transmission to TC1600 at 571-273-8300 to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Aug 3, 2005

Date Aug 3, 2005